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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of Jingrui Wu et al.
Serial No: 10/678,588
Filed: 10/02/2003
For: Yield-Improved Transgenic Plants

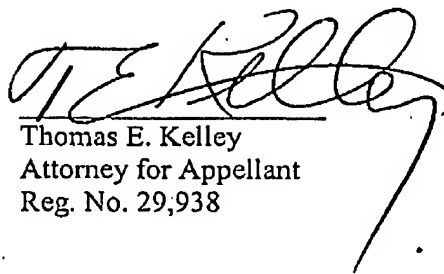
Art Unit: 1638
Examiner: Vinod Kumar

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Commissioner for Patents
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571-273-8300

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The Commissioner has been authorized to charge fees in this application and is specifically authorized to charge the fee for filing a brief in support of this appeal to Monsanto Company Deposit Account No. 143125.



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002/012

Docket No: 38-21(52578)C

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APPELLANT'S BRIEF

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Sir:

This is an appeal from the Final Rejection of claims 1, 2, 5 and 6 in the above-described patent application. Notice of Appeal in this application was received at the Patent & Trademark Office on February 26, 2007, setting the period for filing the brief to expire on April 26, 2007.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any other Appeals or Interferences related to this Appeal. There is however, an outstanding renewed petition to amend priority.

3. Status of Claims

Claims 1, 2, 5 and 6 are the only claims pending and finally rejected in this application at the time of appeal; all other claims are either cancelled or withdrawn.

4. Status of Amendments

The status of the amendment of claims 1, 2, 5 and 6 filed with the Response to Final Rejection on February 26, 2007 is unknown. For purposes of this Brief Appellant assumes that the amendment has or will be entered; the Claims Appendix reflects the claims after amendment. In the possible event that the amendment is not entered, an alternative claims appendix is provided. Arguments are directed to both sets of claims.

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5. Summary of Claimed Subject Matter

The invention as claimed in independent claim 1 is directed to a method for improving yield in a crop exposed to water deficit by providing a transgenic seed for the crop having a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or 3 which are native corn proteins. With reference to Figure 1 it is shown that SEQ ID NO:2 has an addition 8 amino acids, i.e. TIPANGK, in positions 55-61 as compared to SEQ ID NO:3. Support for the general aspects of claim 1 is found in the brief summary of the invention at page 2, lines 10-24 of the specification; support for the specific DNA which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or 3 is found in the detailed description at page 3, lines 1-2. More particularly, the disclosure of a corn plant transformed with DNA which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 is found in Example 1 at page 12, lines 14-23.

In dependent claim 2 the method of claim 1 is specifically applied to corn crops; such a method is supported by Examples 1, 2, 5 and 6.

An aspect of the invention as claimed in independent claim 5 is directed to a method for improving water-deficit survivability of a crop plant comprising introducing into the genome of said plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or 3. Support for the general aspects of claim 1 is found in the brief summary of the invention at page 2, lines 10-24 of the specification; support for the specific DNA which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or 3 is found in the detailed description at page 3, lines 1-2. More particularly, the disclosure of a corn plant transformed with DNA which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 is found in Example 1 at page 12, lines 14-23. See also examples 1 and 2 which illustrate and support improving water-deficit survivability by introducing a DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2.

In independent claim 6 another aspect of the invention is directed to a water-deficit-tolerant, transgenic, hybrid maize plant comprising a recombinant DNA construct expressing a

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gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or 3. This transgenic hybrid maize plant is supported by the specification at page 12, lines 3-9.

In the possible event that the amendment is not entered the above subject matter is not uniquely described by reference to SEQ ID NO:2 and 3 but more broadly described by reference to a consensus amino acid sequence of SEQ ID NO:8 which as shown in Figure 1 is based on the amino acid segment in the central part of four homologous Hap 3 proteins with amino acid sequences of SEQ ID NO:2, 3, 6 and 7.

6. Grounds of Rejection to be Reviewed on Appeal

There are four separate grounds of rejection applying to the claims in this Appeal.

6.(a) First Ground of Rejection – indefiniteness

Claims 1, 2, 5 and 6 stood finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.(b) Second Ground of Rejection – enablement

Claims 1, 2, 5 and 6 stand finally rejected under 35 U.S.C. 112, first paragraph, as lacking enablement.

6.(c) Third Ground of Rejection – written description

Claims 1, 2, 5 and 6 stand finally rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

7. Argument

7.(a) First Ground of Rejection – the indefiniteness rejection

Table of authorities cited: none

This rejection was premised on the use of the term “functionally equivalent” in appealed claims 1, 5 and 6 in view of the use of a consensus amino acid sequence. In view of the presumed entry of the amendment to claims 1, 5 and 6 in which the term “functionally equivalent” is deleted and the consensus amino acid sequence replaced by the amino acid sequence of two native corn proteins, appellant believes that this rejection should be deemed obviated and withdrawn.

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In the event that the amendment to claims 1, 2, 5 and 6 is not entered, applicant submits that the term “functionally equivalent” is readily defined by reference to the water-deficit tolerance trait provided by one of four specifically identified proteins. The claim clearly specifies that the amount of protein to be expressed Reversal of the indefiniteness rejection is respectfully requested, i.e. see claim 1 which is characterized in part by

“a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence identical to the consensus amino acid sequence of SEQ ID NO:8 wherein said gene is constitutively expressed to produce an effective amount of said protein for water-deficit tolerance functionally equivalent to the water-deficit-tolerance imparted by the protein of SEQ ID NO:2 or SEQ ID NO:3 in corn or SEQ ID NO:6 or SEQ ID NO:7 in soybean.”

Appellant submits that a person of ordinary skill in the art, having a transgenic plant that expresses a gene encoding a Hap3 protein, would be readily enabled to

- (a) know whether the amino acid sequence of the protein is identical to the consensus amino acid sequence of SEQ ID NO:8;
- (b) measure the water-deficit tolerance of the transgenic plant;
- (c) prepare a control transgenic plant expressing one of four Hap 3 proteins;
- (d) measure the water-deficit tolerance of the control transgenic plant;
- (e) compare the water-deficit tolerance traits.

Appellant submits that the use of the term “functionally equivalent” in the claims does not render them indefinite but rather points out to a person of ordinary skill in the art what the invention is in such a way as to distinguish the claims from the prior art and to define the scope of protection adored by a patent.

Reversal of the indefiniteness rejections of claims 1, 2, 5, and 6 is respectfully solicited.

7.(b) Second Ground of Rejection - the enablement rejection

Table of Authorities cited: in the argument against the enablement rejection:

Adang v. Fischhoff, 286 F.3d 1346 (Fed. Cir. 2002)

7.(b)(i) General Argument on Second Ground of Rejection as applied to claims 1, 2, 5 and 6

The issue is whether the application has sufficient disclosure to enable a person of ordinary

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skill in the art to practice the claimed invention of claims 1, 2, 5, and 6 without undue experimentation.

Practicing the method of claims 1, 2 and 5 and producing the hybrid maize plant of claim 6 all entail providing a "recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3." To prepare such a recombinant DNA construct reference is made to the specification at page 3, lines 18-28 for a disclosure that

- (a) the transcription factor with amino acid sequence of SEQ ID NO:2 is encoded by the DNA sequence of SEQ ID NO:1; and
- (b) the transcription factor with amino acid sequence of SEQ ID NO:3 is encoded by the DNA sequence disclosed by Li et al., Nucleic Acids Res. 20(5), 1087-1091 (1992).

The specification has disclosed and taught to a person of ordinary skill in the art specific DNA that encodes the transcription factors with an amino acid sequence of SEQ ID NO:2 and 3. The specification also discloses the transformation of corn and soybean plants with recombinant DNA for expressing a gene which encodes a protein having the amino acid sequence of SEQ ID NO:2; see, for instance, Example 1 which discloses the preparation of such a transgenic corn plant and Example 3 which discloses the preparation of a transgenic soybean plant. The specification also discloses how to cross corn plants to make a hybrid corn plant; see page 12, lines 3-9. The Federal Circuit has stated that the issue of enablement involves assessment of whether one of skill in the art could make and use the invention without undue experimentation. See *Adang v. Fischhoff*, 286 F.3d 1346, 1355.

Appellant submits that, having been so taught, a person of ordinary skill in the art is readily enabled to practice without undue experimentation the method of claim 1 which comprises the step of "providing a transgenic seed ... [having] a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3".

Appellant submits that, having been so taught, a person of ordinary skill in the art is readily enabled to practice without undue experimentation the method of claim 2 where the crop is corn.

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Appellant submits that, having been so taught, a person of ordinary skill in the art is readily enabled to practice without undue experimentation the method of claim 5 which comprises the step of "introducing into the genome of said plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3".

Appellant submits that, having been so taught, a person of ordinary skill in the art is readily enabled to prepare without undue experimentation the hybrid maize plant of claim 6 which comprises "a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3".

In the possible event that the amendment to the claims is not entered, Appellant submits that the above described support for enable of the narrow claims characterized by SEQ ID NO:2 and SEQ ID NO:3 serves as a springboard for enabling a person of ordinary skill in the art to practice without undue experimentation the invention with DNA that encodes homologous Hap3 proteins that are characterized by the consensus amino acid sequence.

In view of the above facts and arguments appellant respectfully urges the Board to reverse the enablement rejections of claims 1, 2, 5, and 6.

7.(c) Third Ground of Rejection - the written description rejection

Table of Authorities which are cited in the argument against the written description rejection:

In re Alton, 76 F.3d 1168 (Fed. Cir. 1996);

Enzo Biochem, Inc. v. Gen-Probe, Inc. et al., 296 F.2d 1316 (Fed. Cir. 2002);

Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003)

Capon v. Eshhar v. Dudas, 418 F.3d 1349 (Fed. Cir. 2005)

7.(c)(i) General argument on Third Ground of Rejection as applied to claims 1, 2, 5 and 6 -

The issue is whether the application discloses the claimed subject matter of claims 1, 2, 5, and 6 in such a way as to convey to a person of ordinary skill in the art that applicants, at the time the application was filed, had possession of that claimed subject matter.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.* to ensure that the inventors actually invented what is claimed. If a person of ordinary skill in the art would, after reading the specification,

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understands that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. See *In re Alton*, 76 F.3d at 1175.

Appellant believes that the outstanding written description rejection is based on the prior claims being characterized by a consensus sequence of SEQ ID NO:8. Thus, after entry of the amendment the claims are characterized by the specific amino acid sequences of SEQ ID NO:2 and 3.

Reference is made to Example 1 which discloses the preparation of a transgenic plant with recombinant DNA for expressing a gene that encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2; Example 1 clearly conveys to a person of ordinary skill in the art that the inventors had possession of at least a first embodiment. Reference is made to Figure 1 which shows the amino acid sequence of three homologous proteins, i.e. SEQ ID NO:3, 6 and 7; Figure 1 clearly conveys to a person of ordinary skill in the art that the inventors had possession of at least a three other embodiments. Reference is again made to Figure 1 which shows as SEQ ID NO:8 a consensus amino acid sequence for Hap3 proteins; clearly Figure 1 conveys to a person of ordinary skill in the art that the inventors had possession of multiple other embodiments characterized by the consensus amino acid sequence.

Appellant submits that such a full and precise description of the claimed subject matter more than meets the standard for written description emphasized in *Enzo Biochem* where the Federal Circuit stated that

"[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'"

Enzo Biochem, Inc. v. Gen-Probe, Inc. et al., 296 F.2d 1316, 1324

The Federal Circuit has also expressed that the written description requirement does not require that Applicants recite the precise 'structure, formula, chemical name, or physical properties'. See *Moba v. Diamond* where the Federal Circuit quoting from its prior decision in *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, reemphasized that

"The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'"

Moba, B.V. v. Diamond Automation, Inc., 352 F.3d 1306, 1321,

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Assuming that the claims stand amended so that claims 1, 2, 5 and 6 are characterized by SEQ ID NO:2 and 3, Appellant submits the rejection is contradicted by the evidence disclosed in Example 1 and Figure 1.

In the event that the amendment is not entered so that claims 1, 2, 5 and 6 are characterized by the consensus amino acid sequence of SEQ ID NO:8, Appellant submits that the limited number Hap3 genes that are characterized by the consensus amino acid sequence are readily disclosed to a person of ordinary skill in the art. In this regard the Federal Circuit in the *Capon v. Eshhar* decision recognized an evolution of sophistication in the field of biotechnology. The level of skill in a person of ordinary skill in the art has increased significantly from the date of the Capon and Eshhar inventions up to 2003 the year in which this application was filed. The continuing increase in the level of skill broadens what is described to a person of ordinary skill by a structure, formula or chemical name.

“The ‘written description’ requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution....The Board’s requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.”

Capon v. Eshhar v. Dudas, 418 F.3d 1349, 1358

In view of the statements by the Federal Circuit in *Capon* Appellant submits that a chemical name “Hap3 protein” more precisely defined by the consensus amino acid sequence of SEQ ID NO:8 is more than adequate for meeting the written description requirement for claims 1, 2, 5 and 6.

In view of the above arguments Appellant respectfully solicits reversal of the rejection of claims 1, 2, 5 and 6 for lack of written description.

8. Claims appendix

Appended hereto is a copy of the claims (amended after final rejection) to be reviewed on appeal. In the possible event that the amendment an Alternative Claims Appendix is also appended.

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9. Evidence appendix

There is no evidence appendix.

10. Related Proceedings appendix

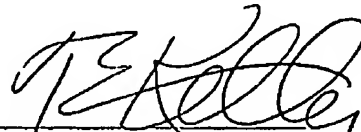
There is no related proceedings appendix.

11. Certificate of Service

There is no certificate of service

In view of the foregoing general arguments, it is respectfully requested that the Board of Patent Appeals and Interferences reverse all of the final rejections of the appealed claims 1, 2, 5 and 6.

Respectfully submitted,



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Claims Appendix

On the assumption that the amendment after final was entered, below is a copy of claims 1, 2, 5 and 6 which are to be reviewed in this appeal.

1. A method for improving yield in a crop exposed to water deficit by providing a transgenic seed for said crop wherein said transgenic seed has a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3.
2. A method of claim 1 wherein said crop is corn.
5. A method for improving water-deficit survivability of a crop plant comprising introducing into the genome of said plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3.
6. A water-deficit-tolerant, transgenic, hybrid maize plant comprising a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3.

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Alternative Claims Appendix

On the possibility that the amendment after final was not entered, below is a copy of claims 1, 2, 5 and 6 which are to be reviewed in this appeal.

1. A method for improving yield in a crop exposed to water deficit by providing a transgenic seed for said crop wherein said transgenic seed has a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence identical to the consensus amino acid sequence of SEQ ID NO:8 wherein said gene is constitutively expressed to produce an effective amount of said protein for water-deficit tolerance functionally equivalent to the water-deficit-tolerance imparted by the protein of SEQ ID NO:2 or SEQ ID NO:3 in corn or SEQ ID NO:6 or SEQ ID NO:7 in soybean.
2. A method of claim 1 wherein said crop is corn, soybean, canola, wheat, rice, cotton or grass.
5. A method for improving water-deficit survivability of a crop plant comprising introducing into the genome of said plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence identical to the consensus amino acid sequence of SEQ ID NO:8 wherein said gene is constitutively expressed to produce an effective amount of said protein for water-deficit tolerance functionally equivalent to the water-deficit-tolerance imparted by the protein of SEQ ID NO:2 or SEQ ID NO:3 in corn or SEQ ID NO:6 or SEQ ID NO:7 in soybean.
6. A water-deficit-tolerant, transgenic, hybrid maize plant comprising a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence identical to the consensus amino acid sequence of SEQ ID NO:8 wherein said gene is constitutively expressed to produce an effective amount of said protein for water-deficit tolerance functionally equivalent to the water-deficit-tolerance imparted by the protein of SEQ ID NO:2 or SEQ ID NO:3.